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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,406	07/19/2001	Yoshihiro Sokawa	55600-8004.US00	9683

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EXAMINER	
WORTMAN, DONNA C	

ART UNIT	PAPER NUMBER
1648	19

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,406	SOKAWA ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1, 2, 4-11, and 13 were amended in Paper No. 18 filed 21 July 2003. Claims 1-11 and 13-15 are pending and under examination.

As a result of the amendments to the claims, the rejections under 35 USC 112, second paragraph, are withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 11, 13-15 are rejected under 35 U.S.C. 102(e) as anticipated by US Patent 6,372,206 to Soos et al., essentially for reasons of record. Soos et al. disclose the use of a therapeutically effective amount of orally administered ovine interferon-tau for treatment of viral disease, including hepatitis C (see, e.g., col. 4, lines 25-60). Soos et al. also disclose advantages of oral administration of interferon-tau, including lower level of anti-interferon antibodies in orally treated subjects as compared to those treated with injected interferon-tau (col. 9, lines 5-24, e.g.). Soos et al. disclose formulations of interferon-tau that are suitable for oral administration, including tablets, capsules, slow release preparations, and liquids, e.g. (col. 15, lines 3-40), as well as therapeutically effective dosages (e.g., col. 4, lines 33-36; col. 15, lines 41-53). Soos also exemplifies administration of an IFN-tau solution. The orally administered interferon-tau compositions of Soos et al. are deemed to anticipate those instantly claimed, because the instant claims do not distinguish over the prior art interferon-tau pharmaceutical composition since no particular dosage form or formulation is recited, and because, interpreting the claims in light of the specification, the trials described on pages 16-20 use an orally administered pharmaceutical composition that comprises "a solution" at a concentration of 1 mg/ml that is administered orally with a syringe.

Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,372,206 to Soos et al. as applied to claim 1, above, essentially for reasons of record. Claims 4-10 presently recite an oral delivery composition comprising ovine IFN-τ in a dosage of between 10^8-10^{10} Units (claim 4); greater than about 10^8 Units (claim 5); greater than about 2×10^8 Units (claim 6); greater than about 4×10^8 Units (claim 7);

greater than about 10^9 Units (claim 8); greater than about 4 x 10^9 Units (claim 9); or greater than about 7 x 10^9 Units (claim 10). Soos et al. teach that ovine IFN-τ has therapeutic applications, including an antiviral effect, and efficacy against HCV, as well as antiviral dosages (e.g., col. 4, lines 33-36; col. 15, lines 41-53); it would have been obvious to one of ordinary skill in the art to have formulated an oral delivery composition of ovine IFN-τ with the amounts now recited based on the teachings of Soos et al.

Applicant has argued (1) that the advantages of the invention were unexpected because there was no reasonable expectation that a composition formulated for oral delivery of ovine IFN-τ would actually be effective in increasing blood levels of OAS or blocking the development or the recurrence of HCV in a human patient, and that prior to this work only mouse IFN-τ had been known to be effective in mice; (2) that there was no reasonable expectation that the low cytotoxicity of IFN-τ observed *in vitro* or when administered by injection would be retained by oral administration when administered in doses high enough to increase bloodstream OAS or as high as those recited in claims 4-10; and (3) that dosages formulated to avoid the *tunica mucosa oris*, as recited in claims 2, 3, 11, and 13, diminish antibody formation compared to IFN-τ absorbed through the oral mucosa. Applicant has argued (4) that Soos et al. do not teach or suggest the use of high dosage compositions, such as those recited in claims 4-10, capable of increasing the blood OAS levels for treatment of HCV, do not provide data relating to prevention or treatment of HCV, including data on blood levels of OAS, and do not teach a composition formulation capable of avoiding the tunica mucosa oris. Applicant has argued (5) that the cited reference does not anticipate the claims because

there is no disclosure of IFN-τ dosages effective to increase bloodstream OAS levels or to treat HCV, nor is there a disclosure of the high dosage levels recited in claims 4-10, nor is there disclosure or recognition that any of the formulations disclosed in Soos et al. would be effective to avoid the tunica mucosa oris, so that the claimed subject matter is not anticipated. Applicant has argued (6) that the cited art does not provide motivation to provide dosages at the levels recited in claims 4-10; (7) that the efficacy of orally-administered protein-based medicaments is unpredictable, and no evidence has been provided that would indicate that IFN-τ would be an exception to the unpredictable nature of oral, high dosage level of proteins; (8) that unexpected results are achieved with dosage formulations that avoid the oral mucosal membrane; and (9) that the cited prior art does not enable the claimed invention since it only lists conditions to be treated and dosage levels and does not put the public in possession of the claimed invention; and (10) that higher dosage levels of IFN-τ as instantly claimed would have been obvious to try.

These arguments have been considered but not found persuasive. With respect to points (1)-(10), all of the pending claims are drawn to ovine IFN-τ compositions that are formulated for oral delivery, for which intended use is given no patentable weight. In the absence of evidence to the contrary, the presently claimed compositions as recited in claims 1-3, 11, 13, and 15 are not seen to be any different from the compositions of Soos et al. since Applicant has not demonstrated that the instant compositions are any different from the oral-delivery compositions of ovine IFN-τ disclosed by Soos et al. and that the compositions of Soos et al. would not be effective

to stimulate bloodstream levels of 2', 5'-oligoadenylate synthetase relative to bloodstream levels of 2', 5'-oligoadenylate synthetase prior to treatment (claim 1), or that the oral delivery vehicles of Soos et al. would not be effective to release IFN-τ in the stomach or intestines (claims 2 and 3), or that they would not avoid the *tunica mucosa oris* (claims 11, 13), and/or that they do not comprise ovine IFN-τ as an effective ingredient (claim 13, 14), or that they would not induce 2', 5'-oligoadenylate synthetase activity in animals other than sheep (claim 15).

With respect to claims 4-10, with respect to Applicant's argument that Soos does not provide motivation to provide the high dosage levels claimed, it is noted that the only IFN-τ compositions that Applicant discloses are 1 mg/ml solutions, in which the specific activity is either 0.29-0.44 x 10^8 Units/mg or 4.99 x 10^8 Units/mg, such that the claimed composition comprising the greatest amount of IFN-τ is that in claim 10, which recites an amount equivalent to greater than about 159-240 ml of IFN-τ solution of specific activity of 0.29-0.44 x 10^8 Units/mg, or greater than about 14 ml of IFN-τ of specific activity of 0.29-0.44 x 10^8 Units/ ml. Applicant has provided no evidence or argument as to why 159-240 ml of an IFN-τ solution of specific activity of 0.29-0.44 x 10^8 Units/mg, as disclosed by Soos et al., is an unobvious amount. Further, since no particular dosage form or formulation other than the solution disclosed by Soos et al. is required by the claims, and because Soos et al., like Applicant, discloses oral administration of an IFN-τ of 0.29-0.44 x 10^8 Units/mg (col. 18, line 12), Applicant's compositions are not seen to differ in any unobvious ways from those of Soos et al.,

since all the claims are drawn to IFN-τ compositions that are not limited by intended use and only claims 4-10 require recited amounts of IFN-τ.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw